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October 11, 2000

The Honorable Carol Browner
Administrator
U.S. Environmental Protection Agency
Ariel Rios Building
Room 3000, #1101-A
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Subject: Comments on "Robust Summary on Phosphorous Acid, Cyclic Neopentanetetrayl Diphenyl Ester"

Dear Administrator Browner:

The following comments on the "Robust Summary on Phosphorous Acid, Cyclic Neopentanetetrayl Diphenyl Ester" are submitted on behalf of People for the Ethical Treatment of Animals, Physicians Committee for Responsible Medicine, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These animal protection and environmental organizations have a combined membership of more than nine million Americans.

The phosphorous acid, cyclic neopentanetetrayl diphenyl ester test plan, submitted by General Electric, is a gross violation of the letter and spirit of the EPA's October 14, 1999, guidance letter to HPV participants, specifically violating six of the ten major points of the letter. Most glaringly, this is a plan for a single compound, whose testing is specifically delayed by that October 14 letter until November 2001. In its posted letter of clarification, General Electric states that EPA "requested deferment of testing of individual chemicals unless there were reasons for testing sooner than that." This is false: the October letter specifically states that "individual chemicals (i.e., those not proposed for testing in a category) that require further testing on animals ***shall*** be deferred until November 200 1."

Furthermore, this plan violates the original HPV program framework in which sponsors pledge to evaluate the adequacy of existing data and submit robust summaries for the sponsored chemicals. The phosphorous acid, cyclic neopentanetetrayl diphenyl ester test plan submitted by General Electric ignores existing data and proposes to conduct poorly thought-out tests that will provide little useful information on the risk that phosphorous acid, cyclic neopentanetetrayl diphenyl ester may pose, while causing extensive animal suffering. The plan provides no rationale for the testing, gives no details of the specific testing procedures, and disregards pertinent information on the environmental fate and transport of this chemical. It is shocking that a

company of General Electric's stature would submit such a shoddy piece of work. The phosphorous acid, cyclic neopentanetetrayl diphenyl ester test plan is unacceptable from both a technical and regulatory perspective and should have been absolutely rejected by EPA.

The EPA's double standard regarding animal testing is obvious in the EPA's responses to date to proposed test plans. The EPA sets extremely high standards each time a company proposes to use existing data, SAR's, or categories in order to avoid conducting a test. However, the agency does not require any justification if a company wants to use animal tests – even if, as in the General Electric case, the company proposes to test individual chemicals and ignore the October letter. Further, the EPA has required, in each of its test plan comments to date, that companies respond to the EPA within 60 days with a description of how they intend to incorporate the EPA's comments. Yet the EPA makes no such request of General Electric.

For the third time, we reiterate the request made in our August 21 letter to you that the EPA specifically address our concerns and detail how the agency intends to ensure that the spirit and guidelines of the October 14, 1999, letter are followed. Almost two months after our original request, we have not received any response from the EPA regarding this important matter.

Because we anticipate the resubmission of this test plan at a later date, we are providing further comments. I can be reached at (757) 622-7382, ext. 304, or by e-mail at jessicas@peta-online.org. Correspondence should be sent to my attention at the following address: 4800 Baseline Road, #E104-390, Boulder, CO 80305. I look forward to your response on this important issue.

Sincerely,

Jessica T. Sandler, MHS
Federal Agency Liaison

cc: The Honorable Robert C. Smith
The Honorable F. James Sensenbrenner, Jr.
The Honorable Ken Calvert
The Honorable Jerry Costello
Council on Environmental Quality

Comments

This test plan violates the agreement arrived at by the Environmental Protection Agency (EPA), the Chemical Manufacturers Association, the Environmental Defense Fund, and animal protection representatives. The following points of the agreement, as outlined in the EPA's October 14, 1999, letter to HPV participants, are violated entirely or in part by the phosphorous acid, cyclic neopentanetetrayl diphenyl ester test plan:

> 1. "In analyzing the adequacy of existing data, participants shall conduct a thoughtful, qualitative analysis rather than use a rote checklist approach.
>
> 3. Participants shall maximize the use of existing and scientifically appropriate categories of related chemicals and structure activity relationships.
>
> 5. Participants are encouraged to use ***in*** vitro genetic toxicity testing to generate any needed genetic toxicity screening data, unless known chemical properties preclude its use.
>
> 6. Consistent with the OECD/SIDS program, participants generally should not develop any new dermal toxicity data.
>
> 8. As with all chemicals, before generating new information, participants should further consider whether any additional information obtained would be useful or relevant.
>
> 9. (b) . . .individual chemicals (i.e., those HPV chemicals not proposed for testing in a category) that require further testing on animals shall be deferred until November 2001 to allow for non-animal test replacements for some SIDS endpoints."

This test plan is proposed for an individual chemical (violation of item 9b). Therefore, the test plan must be rejected by the EPA under the HPV program.

In addition, the proposed test plan is nothing more than a rote reproduction of the checkboxes for each chemical outlined in the original HPV guidance (violation of items 1 and 8). A thoughtful evaluation of the feasibility and necessity of the various tests cannot be conducted without some knowledge of the basic properties or application of the chemical. For example, the utility and application of aquatic toxicity tests cannot be judged without knowledge of the chemical's solubility in water. At a minimum, General Electric needs to state the use of the chemical, its physical properties, the order of testing, the data needed to conduct subsequent tests, and specifically refer to the exact method to be used for each human health endpoint test, with information on whether the tests are ***in vivo*** or ***in vitro,*** list the species to be used, outline the exposure method, and list the exposure time.

General Electric also failed to compare phosphorous acid, cyclic neopentanetetrayl diphenyl ester with other similar chemicals to form a group of phenol compounds (violation of item 3). Phosphorous acid, cyclic neopentanetetrayl diphenyl ester is one of many phenyl phosphorus antioxidant stabilizers that are included in the HPV Program, and would logically fall into the same group in the development of a test plan. In our comments on the Tris(nonylphenol) phosphite test plan, we have discussed the development of this category of HPV chemicals'.

The test plan fails to provide a justification for conducting an in *vivo* genetic toxicity study, even though in vitro genetic toxicity tests should be used to generate any needed genetic toxicity screening data, unless known chemical properties preclude their use (violation of item 5).

The test plan calls for a dermal toxicity study, which is also proscribed in the October 14 letter (violation of item 6).

Conclusions

In short, General Electric has submitted a greatly flawed workplan both from a technical and regulatory perspective. It is astounding that a company with the stature of General Electric would submit such a poorly researched, poorly developed test plan. The EPA must require that phosphorous acid, cyclic neopentanetetrayl diphenyl ester be considered for inclusion in a larger substituted phenyl-phophorus group and that General Electric provide additional existing data on phosphorous acid, cyclic neopentanetetrayl diphenyl ester chemistry prior to conducting any animal testing. The test plan must have clear documentation of the testing methods and provide for the evolution of the experimental plan based on early physical and chemical determinations about the compound. As it stands, the EPA must reject this workplan in its entirety due to its blatant violations of the October agreement and the original HPV framework.

[1] Letter to Carol Browner. Comments on the Robust Summary on Tris (NonylPhenyl) Phosphite PCRM. October 11, 2000.